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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,668	02/25/2005	Juergen Haecker	P70348US0	7646

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EXAMINER	
MUL, CHRISTINE T	

ART UNIT	PAPER NUMBER
1797	

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03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,668	HAECKER ET AL.	
	Examiner	Art Unit	
	CHRISTINE T. MUI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *25 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *14 February 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11-4, 6-10 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/22825 to Neukermans (submitted on the Information

Disclosure Statement on 14 February 2006; herein referred 'Neukermans'), in view of WO 02/24320 to Anazawa (submitted on the Information Disclosure Statement on 14 February 2006; herein referred 'Anazawa'), and further in view of USP 5,580,523 to Bard (submitted on the Information Disclosure Statement on 14 February 2006; herein referred 'Bard').

5. USP 7,238,325 is an English Translation of WO 02/24320 and is used as the basis of the rejections.

6. Regarding claims 1-2, the reference Neukermans discloses a microfluidic system that controls the flows of liquids or gas through elongated capillaries that are enclosed along at least one surface by a layer of malleable material. An electrically powered actuator in the system extends toward or retracts a blade from the layer of malleable material to either occlude or open the capillaries. Reservoirs are included in a pouch with the capillaries where supply fluids flow is controlled by the movement of the blades. The microfluidic system permits dispensing at will under microprocessor control at predetermined flow rates, liquids, samples, chemicals, reagents and body fluid and mixing then together and/or reacting for diagnostic medical or analytical tests. The microfluidic system as seen in Figures 3 and 4 includes a base plate with a planar anvil surface from which projects four registration pins and four registration apertures. On top of the anvil surface rests a planar pouch that engages with the registration pins through the apertures of the base plate. The pouch is preferably made of a upper and lower flexible malleable polymeric sheets to outline the reservoirs, capillaries, reaction chambers and a common capillary. The pouch includes at least one reaction chamber

and reservoirs with planar capillaries that communicate directly with and extend outward from the reservoirs (see page 13, lines 23-37). Even though Neukermans discloses capillaries formed between the laminating sheet that are defined by the laminating sheets can have flow restrictors dry or wet etched into the sheets, Neukermans does not specifically disclose the channel structures cut out in at least one surface.

7. Anazawa disclose a micro chemical device with a valve function. The valve function comprises of two members that are bonded together with a groove in the surface of one of the members. When the members are together, the members form a capillary type channel for the transportation of liquids through the device. The members are made of a flexible material so that upon compression there is a deformation of the region around the channel and the channel may be opened or closed so that flow can be regulated (see abstract, column 1, line 54-column 2, line 6, column 2, lines 19-49, column 6, line 57-column 7, line 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the channel or capillary be cut out in the membrane or material so that a channel is easily formed upon joining pieces of the device together instead of drilling or incorporating a tube within the system as a flow pathway for fluids to flow. Neither Neukermans nor Anazawa discloses the first and/or second parts are made of a rigid material made from injection molding technology.

8. Bard discloses a modular reactor system for synthesizing chemical compounds characterized by a uniform temperature throughout the reaction mixture by use of a continuous flow reactor under high pressure. The chip according to Figures 1a-1d uses

a SiO2 substrate to include the reaction chamber formed by photolithograph is processes. The reaction chamber can be formed with plastic material by injection molding or casting techniques to the desired volume. The flow channels are fabricated using photolithography from the other side of the substrate which are provided for communication to the reactor chamber (see abstract, Figures 1a-1d, column 5, lines 19-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the layers of the cassette be made of rigid and flexible material such as plastic to be able initiate flow between the reactors and channels by pressure but allow the cassette to maintain its shape under pressure.

9. Regarding claims 3 and 8, the references Neukermans, Anazawa and Bard disclose the claimed invention. Neukermans discloses a pouch that is made from the upper and lower flexible, malleable polymeric sheets includes at least one chamber and capillaries that are in communication and that extend outward from the reservoir (see page 13, line 31-page 14, line 3). It is interpreted by the examiner that since the pouch is disposed between the laminated polymeric sheets, the reservoirs and capillaries that are formed between the laminated sheets as wells, making the capillaries constructed of a flexible material.

10. Regarding claims 4 and 9-10, the references Neukermans, Anazawa and Bard disclose the claimed invention. Neukermans discloses a valve assembly beneath the capillaries that press against the planar pouch with clamps or springs (see page 14, lines 6-14). It is interpreted that the valves that are beneath the capillaries are actuators

that transmits energy from the spring or claims to the pouch, by applying pressure to the flexible material and initiating flow within the system.

11. Regarding claim 6 and 13-14, the references Neukermans, Anazawa and Bard disclose the claimed invention. Neukermans discloses that flow restrictor that restricts the liquid flow can be formed by dry or wet etching the sheets (see page 15, lines 22-25).

12. Regarding claims 7 and 15-19, the references Neukermans and Anazawa disclose the claimed invention. Neukermans discloses the capillaries may be narrowed between the reservoirs to provide restrictors for the capillaries and may be defined by the laminating sheets. The laminations of the sheets to establish the width and vertical height of the capillaries may be restricted to a few thousandths of an inch making the capillaries very small if desired (see page 17, line 32-page 18, line 3). Furthermore, it can be see in Figure 1, the capillary that is coupled to the actuator is of a larger width than the first segment of the capillary that extends beyond the actuator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the capillaries be of a shallower and larger cross section where it is coupled to the actuator so that as liquid is flowing from a reservoir, the flow of the liquid can enter system at a lower flow rate, not creating flow restriction and not creating a turbulent flow that may create excess bubble formation or mixing of reagents.

13. Claims 5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neukermans, Anazawa and Bard, and further in view of USP 6,261,006 to Linnemann et al (herein referred 'Linnemann').

14. Regarding claims 5 and 11-12, the references Neukermans, Anazawa and Bard disclose the claimed invention except for where the actuators are membrane pumps. Linnemann discloses a micro membrane pump that comprises of a pump membrane, a pump body and an inlet and outlet openings. The flexible pump membrane can pumps fluids through the device using piezoelectric forces causing s deformation of the membrane that produces a pumping effect (see abstract, column 2, lines 10-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use membrane pumps as a means of pump or move fluids within the cassette device so that upon changing pressure of the membrane, the fluids are able to move within the cassette instantaneously when desired rather than depending on gravity or an equilibration of pressure within the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797